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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,493	06/22/2001	Gregor Cevc	500.1013	7718

21874 7590 05/27/2004

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/887,493	CEVC, GREGOR	
	Examiner	Art Unit	
	Susan Coe	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *06 May 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-6,9,12-14,21-24,35,39-41,44-46,51,54,76 and 83-85*.

Claim(s) withdrawn from consideration: *52,53,55-75 and 77-82*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

SUPPLEMENT TO ADVISORY ACTION

1. The amendment filed May 6, 2004, has been received and will be entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. All of applicant's arguments regarding the 103 rejection of record have been fully considered but are not deemed persuasive. Applicant argues that DE 44 47 287 does not teach or suggest a formulation where the amount of corticosteroid used is above 0.1% by weight. Applicant argues that a person of ordinary skill in the art would not arrive at a dosage of this amount because it is known in the art that higher dosages of topical corticosteroids cause side effects. Applicant provides the review article by Reazzini to show that determining the correct dosage of a topical corticosteroid that does not cause side effects is difficult. However, the reference itself states that hypersensitivity to topical corticosteroids is prevalent when dosages are used that are between 0.2 and 5% (see page 52, second column, first full paragraph). Thus, this reference shows that a dosage of below 0.2% was known in the art at the time of the invention to be a safe dosage for a topical corticosteroid. Therefore, using these dosages in the topical composition if DE '287 would have been obvious because they are known to be safe dosages.

Applicant also argues that currently FDA approved topical corticosteroid compositions do not contain more than 0.05% of the corticosteroid. However, applicant only provides data showing formulations for clobetasol, this does not translate to all topical cortiosteroids. In addition, there is no explanation why a person of ordinary skill in the art would not be motivated

to increase the dosage of clobetasol especially in view of Reazzini disclosure that dosages below 0.2% do not produce side effects.

Thus, for these reasons and the reasons discussed in previous rejections, the claims are still considered obvious over the combination of DE '287 and US 5,322,685.

3. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan D. Coe, Examiner
May 21, 2004